REMARKS

1. Claim Rejection -- 35 U.S.C. § 102(b)

Claims 1-6, 11-15 and 20-22 stand rejected under 35 U.S.C. § 102(b) ("Section 102(b)") as being anticipated by United States Patent No. 4,963,360 to Argaud ("Argaud"). Applicant respectfully traverses this ground of rejection.

An invention is unpatentable under Section 102(b) if "the invention was . . . in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States." A Section 102(b) rejection is only appropriate, however, where the "reference fully discloses in every detail the subject matter of a claim." *Application of Foster*, 383 U.S. 966 (1966). For the reasons set forth below, Applicant submits that the reference cited by the Examiner does not teach each and every element of the claimed invention, as amended, and thus does not bar the claimed invention as a public use of the invention more than one year prior to the date of application.

Claims 1 and 22, as amended, recite "a temperature modification apparatus capable of controlling and selectively modifying a magnitude and duration of heat to achieve selective, precise, on-demand delivery of said analgesic through said skin." Applicant finds no mention of this element in Argaud, nor any equivalent thereof.

Argaud teaches an exothermic package body having a carrier layer comprising a medicinal component, and an exothermic layer which develops heat when exposed to the air to enhance absorption of the medicinal component through the skin, hence improving medicinal effects. Argaud fails to disclose a temperature modification apparatus capable

of achieving selective, precise, on-demand delivery of an analgesic through the skin, as claimed by the present application.

Indeed, although a user may control an amount of heat applied by the exothermic package body described and claimed in Argaud by varying the duration of time during which the package body is used, the Argaud package body itself is incapable of controlling a magnitude and duration of heat to achieve selective, precise, on-demand analgesic delivery, as claimed by the present invention. As the present application indicates, drug absorption rates depend on a number of factors, each of which must be precisely regulated to enable rapid and effective drug administration while preventing drug overdose. While Argaud discloses an apparatus capable of increasing drug administration rates, the apparatus itself fails to implement any feature that enables specific temperature regulation capable of precisely controlling and possibly reducing rates of drug delivery, as claimed by the present invention.

Dependent claims 2-10 and 20-21 add structural limitations to the temperature modification apparatus referenced in independent claim 1. Although the originally filed disclosure supports a broader range of structures (see Specification, p. 13-16), the structural limitations set forth in the dependent claims provide adequate enablement for the temperature modification apparatus of the present invention. As Argaud neither discloses nor suggests a temperature modification apparatus as defined by the present disclosure and claim set, Argaud fails to anticipate the present invention.

Claims 2-6, 11-15 and 20-21 add further limitations to otherwise allowable subject matter, and thus are also not anticipated by the cited reference.

Accordingly, Applicant respectfully requests withdrawal of the rejections of claims 1-6, 11-15 and 20-22 under Section 102(b).

2. Claim Rejection -- 35 U.S.C. § 103(a)

Claims 1, 19 and 23 stand rejected under 35 U.S.C. §103(a) ("Section 103(a)") as obvious in view of Argaud.

An invention is unpatentable under Section 103(a) "if the differences between the subject matter sought to be patented over the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains."

To establish a *prima facie* case of obviousness, three criteria must be met. "First, there must be some suggestion or motivation . . . to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations." MPEP § 2142.

As discussed above, claim 1, as amended, recites "a temperature modification apparatus capable of controlling and selectively modifying a magnitude and duration of heat to achieve selective, precise, on-demand delivery of said analgesic through said skin." Applicant finds no mention or suggestion of these elements in the cited references, nor any equivalent thereof.

Indeed, although Argaud discloses an apparatus capable of increasing drug absorption performance, Argaud neither discloses nor suggests an apparatus having a temperature regulation system that achieves selective, precise, on-demand drug delivery, as claimed by the present application. Instead, Argaud emphasizes the ability of the

exothermic layer to develop heat when brought into contact with air, thereby increasing drug delivery rates. Argaud, however, fails to mention or suggest that the apparatus may control, and possibly limit, such drug delivery rates.

In addition, the problem solved by Argaud is distinct from that solved by the present invention. Argaud seeks to increase rates of drug absorption and delivery by artificially increasing the temperature of the drug and/or skin. Contrarily, the present invention seeks to control rates of drug absorption and delivery by precisely regulating heat produced by the apparatus, which heat may be increased or limited as appropriate.

As Argaud fails to suggest an apparatus capable of controlling the heat produced and applied thereby as claimed by the present invention, the present invention is not obvious in view of Argaud.

As claims 19 and 23 add further limitations to otherwise allowable subject matter, such claims are also not obvious in view of the cited reference.

Accordingly, Applicant respectfully requests withdrawal of the Examiner's rejections of claims 1, 19 and 23 as obvious in view of Argaud under Section 103(a).

CONCLUSION

Based on the foregoing, Applicant respectfully submits that the deficiencies in the application have been corrected and that the proposed claims are neither anticipated nor rendered obvious by the prior art references cited by the Examiner. As such, Applicant believes that the claims are now in a condition for allowance, and action to that end is respectfully requested.

If any impediments to the allowance of this application for patent remain after the above amendments and remarks are entered, the Examiner is invited to initiate a telephone conference with the undersigned attorney of record.

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Respectfully submitted,

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